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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,988	02/09/2004	J. Daniel Raulerson	MED-0014 (49962.00059)	1295
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Fox Rothschild LLP Blue Bell 2000 Market Street Tenth Floor Philadelphia, PA 19103			EXAMINER FLICK, JASON E	
			ART UNIT 3763	PAPER NUMBER
			MAIL DATE 03/01/2010	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/775,988

Applicant(s)

RAULERSON ET AL.

Examiner

JASON FLICK

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25, 27-34, 40-44, 47 and 48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25, 27-34, 40-44, 47 and 48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 February 2004 and 01 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-940)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Examiner acknowledges the reply filed on 11/09/2009 in which claim 25 has been amended. Claims 1-24 and 26 have been canceled. Currently, claims 25, 27-34, 40-44, 47, and 48 are pending for examination in this application.

Specification

2. The amendment filed 11/09/2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "Catheter-engaging surfaces of the top and bottom faces are seen to be free of sharps that otherwise would damage the catheter(s) upon clamping." (page 2, paragraph [0026]). Applicant's representative relies on Figures 1, 1A, 6, 8, and 9 for support. However, the examiner does not concur with this statement. One of ordinary skill in the art would not find support for this limitation based on the drawings alone. Furthermore, given the broadest reasonable interpretation, it could be determined that any edge on the structure could be construed as a "sharp."

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 25 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The new matter presented in the claim is as follows: "Catheter-engaging surfaces of the top and bottom faces are seen to be free of sharps that otherwise would damage the catheter(s) upon clamping." (page 2, paragraph [0026]). Applicant's representative relies on Figures 1, 1A, 6, 8, and 9 for support. However, the examiner does not concur with this statement. One of ordinary skill in the art would not find support for this limitation based on the drawings alone. Furthermore, given the broadest reasonable interpretation, it could be determined that any edge on the structure could be construed as a "sharp."

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. The examiner acknowledges the amendment to claim 25 with regards to the previous 35 U.S.C. 112, second paragraph. This amendment sufficiently overcomes the rejection, therefore the previous 35 U.S.C. 112, second paragraph rejection of claim 25 is withdrawn.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 25, 27-33, 40-44, 47, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lavielle (USPN 4,514,882).

11. [Claims 25, 27-31, 33, 47, and 48] Lavielle teaches a catheter clamp comprising: a body (figure 1) of unitary construction having: a first portion having a first top face sized to retain at least one catheter thereon (figure 1, item 1); a second portion having a second top face sized to retain at least one catheter thereon (figure 1, item 2); a single

hinge directly connecting the first portion and the second portion (figure 1, item 3), such that the first portion is disposable to face toward the second portion when the first portion is pivoted about the hinge toward the second portion and such that the at least one catheter is frictionally engaged (gripping means; column 2, lines 37-42) by and retainable between the first and second top faces in a non-damaging manner (figure 3; column 1, lines 65-68 and column 2, lines 1-2); wherein each of the first and second top faces further comprises, prior to engaging the at least one catheter, a recessed area disposed between the hinge and the locking member (free end portion) (figure 1, item 11), wherein both of the recessed areas are sized to accept at least two catheters (figure 3); both recessed areas further comprising at least one rib extending from the recessed area toward the other of the first and second top faces (figure 1, item 10); and a locking member for releasably locking a free end portion of the first portion to the second portion upon the first and second portions being relatively pivoted together about the at least one catheter (figure 1, items 7 and 8). Although Lavielle does not specifically disclose the first and second portions having a catheter-engaging surface free of sharps, Lavielle discloses "The mating surfaces...equipped with notches or projections, the shapes, sizes and dispositions of which may vary widely" (column 1, lines 65-68). Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the structure taught by Lavielle such that the catheter-engaging surface was free of sharps in order to ensure minimal damage to structures between the surfaces.

12. [Claims 40-44] Lavielle teaches the limitations of claim 47, upon which claims 40-44 depend. In addition, Lavielle discloses the clamp further comprising the locking member for releasably connecting the free end of the first portion to second portion comprises the first portion having a slot (figure 1, item 8), and the locking member of the second portion is a vertically projecting tab, wherein the vertically projecting tab is positioned to be releasably inserted into the slot for locking thereto, faces away from the hinge and includes a ledge that latches to an edge of the slot, and is adapted to be biased toward the hinge permitting manual deflection thereof for release; wherein a top portion of the surface of the tab faces away from the hinge is beveled (rounded) above the locking latch (figure 1, item 7).

13. [Claim 32] Lavielle teaches the limitations of claim 25, upon which claim 32 depends. Although Lavielle discloses the clamp is constructed of a plastic material, the use of polypropylene is not specifically disclosed. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to construct the clamp using polypropylene, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

14. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lavielle (USPN 4,514,882), in view of Turturro et al. (USPN 6,331,165).

15. [Claim 34] Lavielle discloses applicant's entire basic inventive concept substantially as claimed with the exception of the second portion comprising a gripping ring disposed distal from the hinge. Turturro shows this feature, a gripping ring distal of

the working end of a medical device, to be old in the medical devices art. At the time of applicant's invention it would have been obvious to one of ordinary skill in the art to add a gripping ring to catheter clamp distal from the hinge in order to easier grip the device when unlocking and operating the clamp.

Response to Arguments

16. Applicant's arguments filed 11/09/2009 have been fully considered but they are not persuasive. Applicant's representative asserts that the prior art of record does not disclose the invention as claimed.

17. Examiner has fully considered the applicant's arguments but they are not persuasive. It is the examiner's position that given a careful reading, the claims do not distinguish over the prior art of record.

18. Applicant's representative asserts that Lavielle does not teach first and second portions of a catheter clamp which have a surface free of sharps. The examiner respectfully disagrees. As noted in the rejection above, Lavielle explicitly states the mating surfaces have "gripping means" and are "equipped with notches or projections, the shapes, sizes and dispositions of which may vary widely" (column 1, lines 65-68; column 2, lines 37-42). Lavielle goes on to disclose these structures are non-damaging (column 2, lines 1-2). Therefore, modifying the structure disclosed by Lavielle, as stated in the rejection above, would be obvious to one of ordinary skill in the art.

19. Therefore, the examiner asserts the prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial

limitations currently in the claims. Therefore the standing rejections are proper and maintained.

Conclusion

20. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JASON FLICK whose telephone number is (571)270-7024. The examiner can normally be reached on Monday through Thursday, 7:00am to 5:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. F./
Examiner, Art Unit 3763
02/23/2010

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763